K050144

MAR 3 - 2005

510(k) Summary

Submitter: Glidewell Laboratories
4141 MacArthur Blvd.
Newport Beach, CA 92660

Contact Person
Keith D. Allred
949-440-2683
949-440-2787 (fax)

Date of Application: January 11, 2005

Device Name:

- Trade Name - Prismatik™ Ceramic
- Common Name – Porcelain powder for clinical use
- Classification - II
- Product Code - EIH

Description: The device is comprised of dental porcelain powder that is used in the form of powder or blanks as a part of dental laboratory processes that are used to fabricate porcelain (ceramic) and porcelain (fused-to-metal) dental devices that are custom fitted to conform precisely to patients' models.

Intended Use: The device is indicated for use by dental technicians in the construction of custom porcelain (ceramic) and porcelain (fused to metal) dental restorations for anterior and posterior locations.

Substantial Equivalence: The device is substantially equivalent to other legally marketed devices in the United States. Substantially equivalent devices include the following: Avante Micro Crystal® and OPC® Porcelain (Jeneric/Pentron) and Cerabien ZR Porcelain (Noritake).

Safety and Efficacy: The device functions in a similar manner to other comparative devices and the intended use is the same. The differences between comparative devices are minor and do not raise new safety concerns. The effectiveness and suitability to the intended purpose of the device is assured through wide, general use of similar other predicate devices, and demonstrates the safe use of the device to construct dental restorations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 - 2005

Mr. Keith D. Allred
Glidewell Laboratories
4141 MacArthur Boulevard
Newport Beach, California 92660

Re: K050144
Trade/Device Name: Prismatik™ Ceramic
Regulation Number: 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: January 11, 2005
Received: January 24, 2005

Dear Mr. Allred:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050144

Schedule B

Sample Device Label/Indications for Use Statement

- 510(k) Number (if known):
- Device Name: Prismatik™ Ceramic
- Indications for Use:

For use in prosthetic dentistry to create porcelain (ceramic) and porcelain (fused-to-metal) prostheses.

For use only by or on the order of a dental professional such as a DDS or DMD. Not for use by the general public or OTC.

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K050144